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CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte TING TINA YE, RHODA M. SANTOS,
ELAINE LIM, MAI XUAN TRAN,
HANH DOAN, and SIMON NGOC HUU NGUYEN

Appeal 2008-5974
Application 09/839,065
Technology Center 3700

Decided[1]: April 1, 2009

Before TONI R. SCHEINER, LORA M. GREEN, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving a claim to an intravascular catheter. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

Statement of the Case

Background

"Intravascular catheters are used in a wide variety of relatively non-invasive medical procedures" (Spec. 1, ll. 7-8). The Specification teaches that "[i]n order for the catheter to navigate a patient's tortuous vascular system, it is desirable that intravascular catheters be very flexible, particularly near the distal end" (Spec. 1, ll. 21-23).

The Claim

Claims 1, 3-34, and 41 are on appeal. Independent claims 1, 19, and 41 are representative and read as follows:

1. An intravascular catheter, comprising:
an elongate shaft having a proximal end, a distal end, and a distal tip having a shapeable length that is shapeable by thermoforming techniques, the elongate shaft including:
an inner liner;
a second layer disposed over the inner liner, the second layer extending from the proximal end of the shaft to a distal terminus; wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length;
a third layer disposed over the second layer; and
a fourth layer disposed over the third layer, the fourth layer including a proximal end and a distal end, the distal end of the fourth layer extending to the distal end of the shaft.

19. An intravascular catheter, comprising:
an elongate shaft having a proximal end, a distal end, and a distal tip having a shapeable length that is shapeable by thermoforming techniques, the elongate shaft including:
an inner liner;

a second layer disposed over the inner liner, the second layer extending from the proximal end of the shaft to a distal terminus, wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length;

a third layer disposed over the second layer; the third layer including a single coil region near the distal end of the shaft and a multiple coil region near the proximal end of the shaft; and

a fourth layer disposed over the third layer, the fourth layer including a proximal end and a distal end, wherein the durometer at the proximal end is greater than the durometer at the distal end, the distal end of the fourth layer extending to the distal end of the shaft.

41. An intravascular catheter, comprising:

an elongate shaft having a proximal end, a distal end, and a distal tip having a shapeable length that is shapeable by thermoforming techniques, the elongate shaft including:

an inner liner;

a second layer disposed over the inner liner, the second layer including a first segment extending from the proximal end of the shaft to a distal terminus and a second segment extending from the distal terminus to the proximal end; wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapeable length;

a third layer disposed over the second layer; and

a fourth layer disposed over the third layer, the fourth layer including a proximal end and a distal end, the distal end of the fourth layer extending to the distal end of the shaft.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Nita	US 5,951,539	Sep. 14, 1999
Samson	US 6,090,099	Jul. 18, 2000

The issues

A. The Examiner rejected claims 1 and 41 under 35 U.S.C. § 102(e) as anticipated by Samson (Final Rej. 2-3).

B. The Examiner rejected claims 1, 3-6, 8-11, 13, 14, 15, 17, and 18 under 35 U.S.C. § 103(a) as being obvious over Samson (Final Rej. 3-4).

C. The Examiner rejected claims 1, 3-34, and 41 under 35 U.S.C. § 103(a) as being obvious over Samson and Nita (Final Rej. 4-5).

A. 35 U.S.C. § 102(e) over Samson

The Examiner found that

> Samson . . . discloses a catheter comprising an elongated shaft, having a proximal end, a distal end and a distal tip, wherein the shaft includes an inner liner, a second layer disposed on the inner layer, a third layer disposed on the second layer and a fourth layer disposed on the third layer and a radiopaque marker . . .Wherein the distal tip has a shapable [sic shapeable] length and the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapable [sic shapeable] length.

(Final Rej. 2.)

Appellants contend that the "limitation that the tip is 'shapable' means that it can be shaped, but is not necessarily shaped. This limitation describes a structural characteristic of the product, not a process step" (App. Br. 11).

"Appellants do assert that their product differs structurally from the product of the prior art" (App. Br. 13).

Appellants contend that the "recited claim element of a 'shapeable length that is shapeable by thermoforming techniques' has been expressly ignored by the Examiner . . . The phrase clearly does not recite how the catheter was formed, and is not a product by process recitation. Therefore, a prima facie position has not been established." (*id* at 13.)

In view of these conflicting positions, we frame the anticipation issue before us as follows:

Did the Examiner err in finding that the catheter of Samson comprises a "distal tip having a shapeable length that is shapeable by thermoforming techniques"?

Findings of Fact (FF)

1. Samson teaches "a catheter section made up, desirably, of an outer tubing component and at least one inner stiffener component placed coaxially within that outer tubing component. Between the at least one stiffener component and the outer tubing component is a metallic braided tubing member" (Samson, col. 4, ll. 33-38).

2. Samson teaches a catheter of Figure 2 as reproduced below:

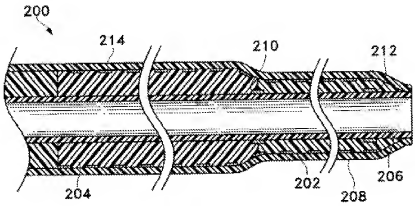

Fig. 2

Figure 2 "shows, in side view, a typical three section catheter" (Samson, col. 4, l. 63).

3. Samson teaches that a "catheter body or section (200) has a pair of inner tubing stiffener members (202 and 204), an optional lubricious sheath (206), and the outer polymeric layer (208)" (Samson, col. 5, ll. 59-61).

4. Samson teaches that the catheter also comprises "a pair of radio-opaque bands, the proximal band is (210) and the distal band is (212)" (Samson, col. 5, ll. 62-63).

5. Samson teaches that the catheter also comprises a "braided tubing member (214). The inner tubing stiffening members or inner stiffening tubing sections (202 and 204) desirably are simple sections of tubing which have been cut to length for placement in the catheter section" (Samson, col. 5, ll. 65-67).

6. Samson teaches that a catheter "must be sufficiently flexible at the distal end to allow passage of the catheter tip through the loops and increasingly small blood vessels" (Samson, col. 1, ll. 40-42).

7. The distal tip of the catheter of Samson shown in Figure 2 is composed of the lubricious sheath 206 and the stiffener member 202 (FF 2-3).

8. Samson teaches that the "'lubricious sheath' (206) may be of any of a variety of lubricious polymers, e.g., polytetrafluoroethylene, FEP, or other fluoro carbon polymers or polysulfones" (Samson, col. 6, ll. 16-20).

9. Samson teaches that the "inner stiffener members sections, or layers (202 and 204) may be of a wide variety of materials but preferably are LLDPE or LDPE perhaps containing a small amount of ethylene vinyl acetate (EVA)" (Samson, col. 6, ll. 11-15).

10. Figure 2 of the Specification is reproduced below:

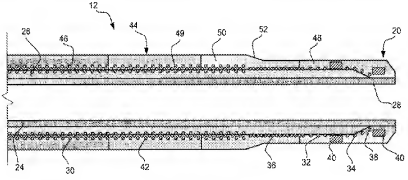

FIG 2

"Figure 2 is an enlarged view of a shaft of the intravascular catheter" (Spec. 4, l. 11).

11. The Specification teaches that "shaft 12 . . . may be more shapable by thermoforming techniques" (Spec. 6, ll. 11-13).

12. The Specification teaches that "[p]referably, inner liner 24 comprises polytetrafluoroethylene (PTFE) . . . inner liner 24 may comprise materials including . . . fluorinated ethylene propylene (FEP) . . . polysu[l]fone" (Spec. 5, ll. 6-14).

13. The Specification teaches that "fourth layer 44 may be comprised of materials similar to those disclosed above, including polymers and metals" (Spec. 7, ll. 21-22). The Specification teaches polymers including "polyethylene (PE), polypropylene (PP), polyvinylchloride (PVC)" (Spec. 5, ll. 11-12)."

14. The Specification teaches that "[a]t distal end 48, the preferred material is a low durometer polymer (e.g. PEBAX 2533) to maintain a soft, atraumatic tip" (Spec. 8, ll. 4-5).

Principles of Law

"A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *In re Paulsen*, 30 F.3d 1475, 1478-79 (Fed.Cir.1994). *See In re Omeprazole Patent Litigation*, 483 F.3d 1364, 1371 (Fed. Cir. 2007). ("Anticipation requires disclosure of each and every claim limitation in a single prior art reference, either explicitly or inherently.")

"Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product." *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977). "Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie

obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products." *Id*. at 1255.

Analysis

Samson teaches an intravascular catheter with an elongate shaft (FF 1-2) which includes an inner liner, lubricious sheath 206 (FF 2-3), a second layer that is set back from the distal end of the shaft, inner tube stiffening layer 204, (FF 2-3), a third layer comprising a braided tubing member 214 (FF 2-3) and a fourth layer comprising stiffening layer 202 which extends to the distal end of the shaft (FF 2-5). Samson teaches that the distal tip is flexible and is composed of layers 202 and 206 (FF 6-7).

The dispute centers on whether the distal tip is "shapeable by thermoforming techniques" (Claim 1). Claim 1and the Specification do not require any particular degree of "shapeability" (FF 10-11).

We agree with Appellants that the "shapeable" limitation is not a product by process limitation and we also agree that the "word 'shapeable' should be understood as meaning 'capable of being shaped'. Thus it is a material property of a portion of the recited device" (Reply Br. 3).

However, the catheter of Samson is structurally identical to the catheter of claim 1, including all of the claimed layers (FF 2-5, 10). Additionally, Samson teaches that the first of the two layers which compose the distal end, the lubricious sheath 206, can be composed of polytetrafluoroethylene (FF 8). This is identical to the material identified as preferred by the Specification for the inner layer (FF 12). Samson teaches

that the second layer of the distal end may be composed of a variety of materials, including LLDPE or LDPE (FF 9). While the Specification prefers PEBAX 2533 (FF 14), the Specification states that "fourth layer 44 may be comprised of materials similar to those disclosed above, including polymers and metals" (Spec. 7, ll. 21-22; FF 13). One of those materials above is polyethylene, which is the material taught by Samson (FF 9, 13).

Since Samson is structurally identical to Appellants catheter, and may be composed of virtually identical materials to those disclosed by Appellants, the only difference is whether the distal tip is inherently "shapeable by thermoforming techniques" (Claim 1).

The Examiner has reasonably established a prima facie case of unpatentability at least based on inherency, thereby shifting to Appellants the burden of proving that the distal tip of Samson would not have been "shapeable". *See In re Best*, 562 F.2d 1252, 1255 (CCPA 1977)("Whether the rejection is based on 'inherency' under 35 U.S.C. § 102, on 'prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products"). On this record, Appellants have proffered no such proof.

We are not persuaded by Appellants' argument regarding the distal terminus of Samson that "[n]o such sections are included in the catheter as shown" (Reply Br. 6). In fact, Samson clearly shows a distal region composed of the inner lubricious layer and the outermost layer which is distal to the second layer (FF 2). This region is the "shapeable length" of the Samson catheter.

We agree with Appellants that "a portion of the catheter, and not just disassembled components" must be shapeable (Reply Br. 6). However, the region of Samson identified above represents a portion of the catheter and that portion is reasonably interpreted as inherently satisfying the "shapeable" limitation since it is composed of the materials reasonably similar or identical to those disclosed in the Specification for the distal tip (FF 8-9, 11-14).

Conclusion of Law

The Examiner did not err in finding that the catheter of Samson comprises a "distal tip having a shapeable length that is shapeable by thermoforming techniques".

B. 35 U.S.C. § 103(a) over Samson

The Examiner rejected claims 1, 3-6, 8-11, 13, 14, 15, 17, and 18 under 35 U.S.C. § 103(a) as being obvious over Samson (Final Rej. 3-4).

Claims 3, 6, 8-11, 13-15, 17, and 18 depend from claim 1. As we have affirmed the rejection of claim 1 over Samson, and Appellants do not identify how Samson fails to teach the dependent claim limitations, we also affirm the rejections of these claims as well.

Appellants separately argue claims 4 and 5, but the argument is that Samson "contains no reference to shapeability, heat setting and heat setting by steam" (App. Br. 14). We are not convinced by these arguments for the reasons already discussed, that the Examiner has provided evidence that reasonably establishes that the distal tip of Samson inherently satisfies these functional recitations. *See In re Cruciferous Sprout Litigation*, 301 F.3d

1343, 1349 (Fed. Cir. 2002) ("It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it.")

C. 35 U.S.C. § 103(a) over Samson and Nita

The Examiner rejected claims 1, 3-34, and 41 under 35 U.S.C. § 103(a) as being obvious over Samson and Nita (Final Rej. 4-5).

As above, claims 3 and 6-18 depend from claim 1. Claims 20 and 23-34 depend from claim 19. Appellants rely upon the same argument regarding the "shapeability" of the distal tip to overcome the obviousness case over Samson and Nita. We note that Nita teaches and prefers the use of PEBAX in the outer polymeric layer (Nita, col. 12, l. 63 to col. 13, l. 1).

As we have affirmed the rejection of claim 1 over Samson, and Appellants do not identify how Samson and Nita fail to teach any other limitations of independent claim 19 or any of the dependent claim limitations, we also affirm the rejections of these claims.

As above, Appellants separately argue claims 4, 5, 21, and 22, but the argument is that the "Examiner has failed to identify where in either reference such properties are disclosed or suggested" (App. Br. 16). We are not convinced by these arguments for the reasons already discussed, that the Examiner has reasonably established that the distal tip of Samson inherently satisfies these functional recitations. *See In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1349 (Fed. Cir. 2002) ("It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it.")

Appellants also separately argue claim 41, but rely upon the argument regarding the "shapeable length". As we have affirmed the rejection of claim 1 over Samson, and Appellants do not identify how Samson and Nita fail to teach any other limitations of independent claim 41, we also affirm the rejection of this claim.

SUMMARY

In summary, we affirm the rejection of claims 1 and 41 under 35 U.S.C. § 102(e) over Samson. We affirm the rejection of claims 1, 4, and 5 under 35 U.S.C. § 103(a) over Samson. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 3, 6, 8-11, 13-15, 17, and 18 as these claims were not argued separately. We affirm the rejection of claims 1, 4, 5, 19, 21, 22, and 41 under 35 U.S.C. § 103(a) over Samson and Nita. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejection of claims 3, 6-18, 20, and 23-34 as these claims were not argued separately

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

Ssc:

CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420